K031634

AUG 2 9 2003

510(k) Summary

This summery is submitted in compliance with 21 CFR 807.92

(a) (1) Submitted by: Scanditronix Wellhöfer GmbH
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Germany

Trade name of the company: Scanditronix Wellhöfer

Contact persons: Thomas Matzen
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Date of preparation: 23 May -2003

(2) Trade name of device: OmniPro I'mRT

Common name: Dosimetry System for Quality Assurance

Classification name: (Accessory to) Radionuclide radiation therapy system, §892,5750; X-ray radiation therapy system, §892,5900; and Medical charged-particle radiation therapy system, §892.5050.

(3) Identification of predicate marketed device:

RIT113 Film Analysis System FDA K935928 12/13/1993

(4) Description of the device:

The Scanditronix & Wellhöfer OmniPro I'mRT system is a system similar to
Radiological Imaging Technology: RIT113 Film Analysis System FDA K935928 12/13/1993

The OmniPro I'mRT system and the marketed predicated product are radiotherapy quality assurance systems designed to measure dose, dose- or intensity-distributions, to analyse these data and to compare the measurement data with calculated dose- or intensity-distributions, especially in the field of Intensity Modulated Radiotherapy.

The OmniPro I'mRT system can consist of

- software (herafter called OmniPro I'mRT)
- hardware supported by OmniPro I'mRT (like detector arrays, filmscanning devices, single detectors, bodyphantoms for positioning and pacing of film and/or detectors or detector arrays).

A typical workflow could looks like this:

1- A treatment planning system (not part of the OmniPro I'mRT system) calculates the dose distribution inside the I'mRT Phantom for a specific IMRT plan.
2- Films are placed in the I'mRT Phantom.
3- The I'mRT Phantom (and the films) is irradiated according to the above IMRT plan. (Radiation device not part of the OmniPro I'mRT system)
4- The films are developped (development machine not part of the OmniPro I'mRT system) and scanned using a film scanner supported by OmniPro I'mRT (e.g. Vidar VXR-12).
5- Exposure is translated into dose, data are visualised in OmniPro I'mRT where data can be analysed
6- The dose plan (point 1-) is imported to OmniPro I'mRT
7- Measured dose and planned dose are compared.
8- The data and/or the result of the comparison are saved and exported (e.g. printed out).

Note that this is just an example to illustrate the general workflow: Steps in the workflow may be left out, others may be altered or some may be added for example if using other detectors than film. In addition to film detector arrays or single detectors are supported.

(5) Intended use:

The intended use of the OmniPro I'mRT system is to:

- verify the treatment plan and delivered dose of intensity modulated or static beams prior to treatment
- verify the intensity maps during IMRT delivery prior to treatment
- verify the absolute dose in given points for IMRT fields.

(6) Technological comparison:

The Scanditronix Wellhöfer OmniPro I'mRT is a Dosimetry System similar to
- Radiological Imaging Technology: RIT113 Film Analysis System FDA K935928 12/13/1993.

Both systems consist of a software supporting hardware. Both allow
1- import of planned data,
2- import of measured data,
3- comparison of measured or planned data with measured or planned data.

Overview over relevant parameters:

Area	RIT113	OmniPro I'mRT
Indication for use	Verifying delivered dose or intensity maps and comparing it with treatment plans especially in intensity modulated radiotherapy (IMRT) treatments	
Used by	Physicists and dosimetry experts in radiotherapy departments	Physicists, dosimetry experts in radiotherapy departments
Design	Analysing- and measuring-software supporting devices like film scanners	Analysing- and measuring-software supporting devices like film scanners
Energy used	Vidar: 95-130 or 190-260VAC, <75W	Vidar 95-130 or 190-260VAC, <75W Lumisys: 100-120V, 50/60Hz, 1.5Amps Or 200-240V, 50/60Hz, 1.0Amps, BIS: 100-240V, 50/60Hz, 0.75-0.35A Dose 1: 100-240VAC, max 40W, typical 15W
Energy delivered	No energy delivered.	No energy delivered
Electrical safety	UL1950 (Vidar Dos. Pro)	EN 60-601, IEC 61010 (Dose 1), CSA C22.2-601 (Dose 1), UL1950 (Vidar Dos. Pro)
Performance	**RIT113**	**OmniPro I'mRT**
Dose/Fluence Map import format	Dicom RTOG BMP TIFF BINARY Vendor specific: - ADAC Pinnacle - CadPlan - additonally different other vendors	Dicom RTOG + vendor specific: - ADAC Pinnacle - CadPlan (Varian)
Film digitizers Support?	Yes. Vidar (VXR-12, -12plus, -16 Dosimetry Pro)	Yes. Vidar (VXR-12, -16, 16 Dosimetry Pro) Lumisys
Calibration	Signal to dose	Signal to OD, OD to Dose
Body Phantom support	Yes (in principal all available phantoms)	Yes. All phantoms that allow filmpositioning perpendicular to room coordinate system.
Support of data from Detector Array measurements	Yes. Import of data from a number of Digital Portal imagers - Varian a500 - Varian Portalvision - Elekta - Kodak CR	Yes. Controlling the Beam imaging system (I'mRT QA).
Support of data from single detector measurements	?	Yes
Analysing Tools		
Alignment (film/plan)	yes	Yes

Difference	Yes	Yes
Sum	yes	Yes
Multiplication	No (?)	Yes
Profile Comparison	Yes	Yes
Isodose comparison	Yes	Yes
Gammamethod	No (?)	Yes
Plan-plan intercomparison	Available for most operations	All operations
Plan –film intercomparison	All operations	All operations
Film-film intercomparison	Available for most operations	All operations

Comment to the above comparison list:
There are no principal differences between the systems, neither regarding support of measured data, import of data or tools for comparing or analysing of data.
The differences regarding performance are the following

1- Import of data: The RIT113 system supports more vendor specific dataformats than OmniPro I'mRT. OmniPro I'mRT supports rather data formats according to standards (DICOM, RTOG), since more and more vendors support either of the standards.
2- Film scanners: RIT113 does not support the VXR-16 scanner and Lymisys scanners. The use and the specifications of those scanners however are very similar to the VXR-12 and VXR-16 Dosimetry Pro scanners, parameters like geometric resolution, data deepth (12 or 16 bits) may vary slightly.
3- Calibration: The RIT113 performs the calibration in one step from signal to dose, in OmniPro I'mRT the calibration is performed in two steps: First from signal to optical density and then from optical density to dose. The two step method has the adventage that the calibration curves for the scanner and the film can be checked independently from each other.
4- Bodyphantom support: Both systems support almost all phantoms on the market (mounting of film in planes parallel or perpendicular to the room coordinate system). This way of mounting films is seen as the standard and all parameters that can be checked with film can be checked using this standard set up.
   There is the Gammex 469 phantoms where the film is mounted in a a helix inside a cylinders. This phantom is not supported by OmniPro I'mRT. However this does not limitate the intended use in any way, since with films using the standard set up all parameters to be checked with film can be measured.
5- Support of data from Detector Array measurements: RIT113 supports the import of data measured with a detector array (portal imaging systems), OmniPro I'mRT supports the whole measurement process of the detector array (I'mRT QA). The detector arrays supported by RIT113 are optmized for optimal imaging quality. The I'mRT QA has been developed for dosimetric purpose.
   The principal of use is very similar: Both systems give a signal that is proportional to the intensity map. The signal can be imported to the main application and than be compared with a planned intensity, fluence- or dose distribution.

Both systems are gantry mounted, the I'mRT QA can additionally be placed onto the treatment couch.

6- Support of data from single detector measurements: There are two important tasks in verifying IMRT plans: Verifying the relative dose or intensity map (done with film or detector array), verifying the absolute dose in one single point. Therefore OmniPro I'mRT supports measurements done with a single detector.
The Dose 1 (510(k) K000209) or other absolute dosimetry measurement systems can be used.

7- Analysing tools: The tools for IMRT field verification are almost identical: Three of the most important tools/operations Film alignment, Subtraction and isodose comparison are available in both systems. In OmniPro I'mRT even multiplication and the gammamethod (see Daniel A. Low et al: A technique for the quantitative evaluation of dose distribution, Med Phys 25 (5) May 1998) are available, allowing the comparison of two datadistributions in one single step instead of using two different methods (subtraction and isodose comparison) in two steps.

(6b) (1) Non-Clinical tests:

The OmniPro I'mRT system consists of software and hardware. The hardware supported is mainly the same as supported by the RIT113. Also the data formats (and thereby the planning systems) supported for import are mainly the same.
Since the accuracy of the measured och planned data is limited by the technical specification of the measurement device or the raw planning data rather by the software reading these data we can conclude that a non-clinical comparison tests in a laboratory between the RIT113 and the OmniPro I'mRT system is not necessary to show equivalence.

To minimize potential electrical hazards, Scanditronix Wellhöfer adheres to recognized and established industry practice, and all devices are subject to final performance testing.
All electrical devices of the OmniPro I'mRT System are designed for conformance with national and international standards
Dose 1:
Mechanical stability: IEC 61010
Electrical safety: CSA 22.2-601.1, EN 60-601, IEC 61010
EMC: EN 55022, FCC Class B
BIS^{2G} / I'mRT QA:
IEC 601-1 standards for electrical isolation and leakage current, EN 60 601-1-2, Electromagnetic compatibility.

The quality assurance system at Scanditronix Wellhöfer GmbH is certified since 1995 according to DIN EN ISO 9001 and DIN EN 46001.

(2) Clinical tests:

Due to the fact that the system is a quality assurance device in radiation treatment not directly involved in the delivery of the treatment radiation, no clinical testing was performed.
However, the device was tested in clinical environment by medical physicists to evaluate the overal performance (indication for use) of the system.

(3) Conclusion:

Testing operational parameters indicates that the Scanditronix Wellhöfer OmniPro I'mRT System is save, that it fulfills the intended use.
The technological comparison with the predicate device RIT113 Film indicates that it is equivalent with the product RIT113.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

Scanditronix Wellhöfer GmbH
% Mr. Thomas Matzen
Official Correspondent
Scanditronix Wellhöfer AB
Stålgatan 14, 75450 Uppsala
SWEDEN

Re: K031634
Trade/Device Name: OmniPro I'mRT System
Regulation Number; 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: May 5, 2003
Received: June 3, 2003

Dear Mr. Matzen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Ver/ 3 - 4/24/96
Applicant: Scanditronix Wellhöfer GmbH
510(k) Number (if known): K031634
Device Name: OmniPro I'mRT
Indications For Use:

Intended Use

The intended use of the OmniPro I'mRT system is to:

- verify the treatment plan and delivered dose of intensity modulated or static beams prior to treatment
- verify the intensity maps during IMRT delivery prior to treatment
- verify the absolute dose in given points for IMRT fields.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031634

Prescription Use ✓